K121551

5. 510(K) SUMMARY

OCT 23 2012

NEURO™ STRUCTURES

Submitter's Name:	NeuroStructures
Submitter's Address:	63 Bovet Road, Suite 135 San Mateo, CA 94402
Submitter's Telephone:	800-352-6103
Contact Name:	John Stephani
Date Summary was Prepared:	18 May 2012
Trade or Proprietary Name:	Resolute™ Facet Screw System
Common or Usual Name:	Screw, Fixation, Bone
Classification:	Unclassified
Product Codes:	MRW
Classification Panel:	Orthopedic and Rehabilitation Devices Panel
Predicate Device:	Spineology® Capture™ Facet Screw System (K092464) NuVasive® Triad® Facet Screw System (K020411)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Resolute Facet Screw System is comprised of various sized single-use, non-sterile facet screws that are designed to provide bilateral transfacet fixation of the lumbar facet joints. The system consists of titanium alloy (6AL-4v-ELI per ASTM F136) screws in fully threaded and partially threaded designs, both of which are cannulated.

INDICATIONS FOR USE

The Resolute Facet Screw System is intended to stabilize the spine as an aid to fusion by transfacet fixation. The device is indicated for posterior surgical treatment of any or all of the following at the L1 to S1 (inclusive) spinal levels: Spondylolisthesis, Pseudoarthrosis or failed previous fusions which are symptomatic; Degenerative Disc Disease (DDD) as defined by back pain of discogenic origin with degeneration of disc confirmed by history and radiographic studies and/or degenerative disease of the facets with instability.

TECHNICAL CHARACTERISTICS

The Resolute Facet Screw System screws are manufactured from titanium alloy (6AL-4v-ELI per ASTM F136), similar to the referenced predicate devices. No new technical characteristics are being introduced with this product.

PERFORMANCE DATA

Cantilever testing and engineering analysis was completed on the Resolute Facet Screw System.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that Resolute Facet Screw System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Neurostructures, LLC
% Empirical Testing Corporation
Ms. Meredith May, MS
4628 Northpark Drive
Colorado Spring, Colorado 80918

OCT 23 2012

Re: K121551
Trade/Device Name: Resolute Facet Screw System
Regulatory Class: Unclassified
Product Code: MRW
Dated: September 06, 2012
Received: October 15, 2012

Dear Ms. May:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Enclosure

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K121551

4. INDICATIONS FOR USE STATEMENT

Device Name: Resolute Facet Screw System

The Resolute Facet Screw System is intended to stabilize the spine as an aid to fusion by transfacet fixation. The device is indicated for posterior surgical treatment of any or all of the following at the L1 to S1 (inclusive) spinal levels: Spondylolisthesis, Pseudoarthrosis or failed previous fusions which are symptomatic; Degenerative Disc Disease (DDD) as defined by back pain of discogenic origin with degeneration of disc confirmed by history and radiographic studies and/or degenerative disease of the facets with instability.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121551